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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/093,972	06/09/98	NYCE	J P6641031

HM22/0824  
PRETTY SCHROEDER & POPLAWSKI  
444 S FLOWER ST  
19TH FLOOR  
LOS ANGELES CA 90071

EXAMINER

EPPS, J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/99

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/093,972**

Applicant(s)  
**Johnathan Nyce**

Examiner  
**Janet Epps**

Group Art Unit  
**1635**



☒ Responsive to communication(s) filed on Jun 9, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-107 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-107 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*Handwritten signature: A. Epps*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Sequence Information***

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. There is no sequence listing submitted in either computer readable form or as a paper listing for the instant application.

Any response to this Office Action should include an adequate response in compliance to the sequence requirements described above. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

### ***Election/Restriction***

2. This application discloses pharmaceutical compositions comprising antisense oligonucleotides which target the expression of mRNA encoding adenosine A<sub>1</sub>, A<sub>2b</sub>, and A<sub>3</sub> receptors. Methods of treating conditions associated with the expression of these genes by administration of these antisense oligonucleotides are also disclosed. Claims 1-107 are generic claims which can be applied separately to antisense oligonucleotides targeting mRNA encoding adenosine A<sub>1</sub>, A<sub>2b</sub>, and A<sub>3</sub> receptors. Since adenosine A<sub>1</sub>, A<sub>2b</sub>, and A<sub>3</sub> receptors are independent genes, which are transcribed into chemically different mRNAs with unique 3 dimensional folding

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patterns and different accessible cleavage sites for nucleic acid molecules (ribozyme activity), antisense/ribozymes designed to target these individual genes would comprise a distinct set for each gene. Therefore, each set of nucleic acid molecules designed to regulate the expression of mRNA encoding adenosine A<sub>1</sub>, A<sub>2b</sub>, and A<sub>3</sub> receptors would represent patentably distinct inventions, possessing distinct biological functions, and requiring separate areas of search. For this reason the applicant is required to elect one gene from the group of (I) adenosine A<sub>1</sub> receptor, (II) adenosine A<sub>2b</sub> receptor (III) adenosine A<sub>3</sub> receptor to apply to one of the the following inventions of claims 1-107:

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-64, drawn to pharmaceutical composition, and formulation comprising antisense oligonucleotides targeting an adenosine receptor, classified in class 514, subclass 44.
  - II. Claims 65-107, drawn to *in vivo* methods of delivering a pharmaceutical composition to a target polynucleotide, classified in class 514, subclass 44.
4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense oligonucleotides of invention I can be used a probes for hydridization of nucleic acid encoding adenosine A<sub>1</sub>, A<sub>2b</sub>, and A<sub>3</sub> receptors.

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5. A telephone call was made to Viviana Amzel on 8/11/99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



George C. Elliott, Ph.D.  
Supervisory Patent Examiner  
Technology Center 1600

Janet L. Epps, Ph.D.

August 17, 1999